

EFFICACY REVIEW
Bayer Environmental Science, 1-Year Efficacy Data: 432-EUP-7

DATE: 12/08/04

DP BARCODE: D310931

GLP: No

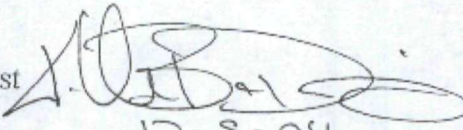
CHEMICAL: Imidacloprid (75.0%)

PURPOSE: The purpose of this review is to provide efficacy data for product registration and for a new use pattern, i.e., Targeted Termite Treatment (T³), for Premise termiticides.

MRID: 46400401. Reid, B; Krygsman, A (2004) Performance Data - The Efficacy of Premise Insecticide Using Minimal Interior Treatment Protocols as Determined in Field Use Research. Project Number: USA03K07/02, Jones10, NC/06. Unpublished study prepared by Bayer Environmental Science. 100p.


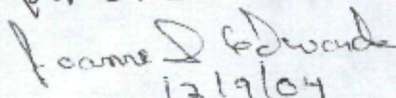
TEAM REVIEWER: Dani Daniel

EFFICACY REVIEWER: Kable Bo Davis, M.S., Entomologist


12-9-04

SECONDARY

EFFICACY REVIEWERS: Mark Suarez, M.S., Entomologist

 13 DECEMBER 2004

12/19/04

Joanne Edwards, M.S., Entomologist

BACKGROUND:

The registrant, Bayer, is submitting one year efficacy data from their current Experimental Use Permit (EUP No. 432-EUP-7) to support their request for the acceptance of a new use pattern for Premise insecticides, i.e. Targeted Termite Treatment (T³). The T³ approach is comprised of complete exterior applications, and interior treatments limited to mandatory

applications of active termite sites and optional treatment of problem areas.

The two year EUP was granted in October, 2003 and allows for the treatment of up to 825 properties. The data collected from this experimental permit is applicable towards the data requirements needed for the Premise 75 WP in Water Soluble Packets (432-1332) label revision to include the T³ approach, and for the registration efficacy requirements of several pending Premise products (432-RGIR, 432-RGTO, and 432-RGIN).

DATA REVIEW:

The following data review is comprised of explanations of materials and methods, and a summation of experimental results containing a table with reformatted data.

The submitted one year EUP data is comprised of data collected from 119 termite infested homes, distributed across 16 states. Each structure was infested with either one of several different species of *Reticulitermes* spp., *Coptotermes formosanus*, or *Heterotermes aureus*.

All treatments used the approved label rates of use for Premise 75 WP Insecticide (0.05% or 0.1%) and were applied by licensed certified applicators who were monitored by either a Bayer representative or a University researcher. Initial applications consisted of full volume, complete outside foundation wall treatments, and targeted indoor active site applications. In addition, optional interior applications were allowed for vulnerable areas.

To monitor the efficacy of the initial application, several inspections were scheduled for each home during the first six months, then every six months for two years, followed by annual visits. A Bayer representative or University researcher were present during the majority of initial inspections and many of the follow-up inspections.

Reported Results:

After initial application of the 119 homes within the EUP, 22 properties required retreatment, i.e. additional insecticide was used at a later date to control termite infestation within the home. From these 22 structures, it was reported that 17 retreatments were due to the certified applicator not following the labeled directions for use during application. This lack of adherence to labeling was either an incomplete initial application or from not treating attached slabs that abut the exterior perimeter of the foundation wall. Another two of the 22 retreatments were as a result of unique construction features that hid interior expansion joints during inspection. Finally, there were three retreatments of homes with standard or predictable construction, and with applicators that followed the label directions.

If counting the 17 properties that required retreatment due to the certified applicator not following label directions during the initial application, the percent control for the first year of the EUP is 81.5%. If the 17 retreatments are not taken into account, the total number of homes considered for the EUP is 102, and the percent control is 95.1%.

Table One. One Year Efficacy of Premise Insecticide Using Minimal Interior Treatment Protocols (EUP No. 432-EUP-7)

Total Properties: 119 (using 17 retreats due to label directions not being followed)		
	Number Retreatments	Percent Control
	22 ^a	81.5%
Total Properties: 102 (not using 17 retreats due to label directions not being followed)		
	Number Retreatments	Percent Control
	5 ^b	95.1%

a. includes 3 standard retreatments, 2 retreatments due to compromised inspections, and 17 retreatments due to lack of adherence to labeling.

b. includes 3 standard retreatments, and 2 retreatments due to compromised inspections.

RECOMMENDATIONS:

The submitted data do not support the acceptance of the new use pattern, Targeted Termite Treatment (T³), for the currently registered product Premise 75 WP in Water Soluble Packets (432-1332), nor do they meet the efficacy requirements for the registration of the pending Premise products 432-RGIR, 432-RGTO, and 432-RGIN. The following comments apply:

1. Because the level of success is based upon the number of retreatments monitored over time, one year of recorded data is not sufficient to base a decision on the efficacy of the T³ approach using Premise insecticides. It is recommended that the results of the current EUP be submitted for review upon completion of the two year permit.
2. In reviewing the submitted data, the percent control varied (81.5% - 95.1%) depending upon whether or not the 17 retreatments that resulted from the lack of label adherence during the initial application were included. Because all initial applications were monitored by a Bayer representative or University researcher, it is the Agency's position that the 17 retreatments be calculated within the percent control resulting in an unsatisfactory 81.5% control. It is recommended that greater care be taken in monitoring future applications to ensure that the label directions were accurately followed, thereby protecting the integrity of the study.